

**REMARKS/ARGUMENTS**

Applicants and Applicants' representative wish to express their thanks to the Examiner for his availability for an Interview on the present case. It is the Applicants intention to present and then elaborate on the Remarks and Arguments provided herein. The present Response shall serve, as a guideline and agenda for the Interview.

Claims 1-3, 5-26, and 32-61 are pending in the application. Claims 4 and 27-31 were previously withdrawn, without prejudice. The following Remarks and Arguments focus on independent claims 1 and 8, but are equally applicable to the patentability of the remaining claims in the application.

Claims 1-3, 5, 9-14, 17-20, and 22-26 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA Irritant Smoke Protocol (the "OSHA reference"), in view of U.S. Patent No. 3,834,241 (Garren '241). Claims 6 and 7 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of U.S. Patent 3,834,241 (Garren '241), and further in view of U.S. Patent No. 5,073,347 (Garren '347). Claim 15 is rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241, and further in view of U.S. Patent No. 3,938,392 (Rodrigues '392).

Claims 8, 16, 21, 32-46, 52, and 57 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and further in view of U.S. Patent No. 3,840,009 (Michaels '009). Claims 36, 48, 49, 51, 58, 60, and 61 are rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and further in view of U.S. Patent No. 5,302,344 (Perlman '344). Claims 50 and 59 are rejected under 35 U.S.C. 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and Perlman '344, and further in view of U.S. Patent No. 6,098,802 (Asa '802). Finally, claim 47 is rejected under 35 U.S.C. § 103(a), as being unpatentable over the OSHA reference in view of Garren '241 and Michaels '009 and further in view of Rodrigues '392.

Applicants respectfully traverse each of the above 35 U.S.C. § 103(a) rejections. Applicants maintain its position that the combination of the OSHA reference and the Garren '241 reference does not render any of the independent claims obvious.

Amended Claim 1 recites an apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein. The apparatus includes a one-piece, polymeric pump and container portion combination, a chemical substance stored in the container portion and which is reactive with the local environment, wherein the polymeric pump is integrally formed as one piece with the container portion and joined seamlessly with the container portion, and an outlet that is severable to direct indicator gas into the local environment. Further, Claim 1 is amended to recite, and highlight, that the pump and the container portion are in fluid communication and define an internal environment that includes the chemical substance and is sealed from the local environment.

Although the OSHA reference discloses a testing apparatus, it does not teach an apparatus that has a polymeric pump portion that is:

- (1) integrally formed as one piece with the container portion;
- (2) joined seamlessly with the container portion; and
- (3) wherein the one-piece, polymeric pump and container portion are in fluid communication and define an internal environment that includes a chemical substance reactive with the local environment and is sealed from the local environment.

The OSHA reference calls, instead, for the use of a specific size pump that is separate from the smoke tube. Garren '241 is cited in the Office Action as cure to the deficiencies of the OSHA reference. Specifically, Garren '241 is cited as disclosing the use of a plastic pump integrated with a plastic pipette and thus, as teaching or suggesting a substitute of the separate pump and glass tube combination in the OSHA reference.

The Examiner has the initial burden of presenting a *prima facie* case of obviousness. M.P.E.P. § 2142-43; see also *In re Peeks*, 612 F.2d 1287 (CCPA 1980). This requires the Examiner to meet three basic criteria. If the Examiner fails to meet any one of these three basic criteria, he has failed to present a *prima facie* case and any rejection based on 35 U.S.C. § 103(a) is improper. Applicants believe that, in the present case, one or more of the these three basic criteria has not been met. Accordingly, the standing rejections under 35 U.S.C. § 103(a) are improper.

(1) *All claim limitations are not taught or suggested by any combination of the cited references.*

A first criteria requires the Examiner to establish that all claim limitations are taught or suggested by the prior art. *In Re Roy*, 490 F.2d 981 (C.C.P.A. 1974). Applicants point out that none of Garren '241, the OSHA reference, and the combination of the two, teaches or suggests a one-piece polymeric structure (and more particularly, a polymeric pump and container portion combination) having two portions that are in fluid communication, define an internal environment that is sealed from the local environment, and stores a chemical substance reactive with the local environment (which limitations are recited in amended claim 1). Although the Garren '241 reference teaches the construction of a polymeric pipette portion, the pipette portion cannot be sealed as required by the present invention (without defeating the dispensing purpose of the pipette).

Garren '241 may indeed teach the use of and desirability of a plastic pipette over a glass pipette but, one skilled in the art would not necessarily recognize such teaching as applying readily to a smoke tube. Specifically, this reference does not necessarily teach the use and desirability of a sealed, integrally formed and seamlessly joined pump-container combination, plastic smoke tube over a glass smoke tube. More importantly, it does not teach one skilled in the art how to join and integrate the pump and container, define a sealed internal environment that includes a reactive chemical substance, and fluidly communicate the pump and container sections. These teachings are provided by the present applicants application only. Without such specific teachings, Garren '241 cannot, therefore, provide to one skilled in the art the motivation and reasonable expectation of allowing for proper "operation of the protocol [for a smoke tube]..." As further explained below, one skilled in the art would recognize that the smoke tube demands a construction providing a sealed environment that includes a reactive substance and a pump-container section which are in fluid communication, and, further, that the teaching of a plastic pipette does not satisfy that demand.

(2) *The suggested combination of cited references does not provide any teaching, incentive, or suggestion to combine these references.*

In any event, a combination of prior art teachings, such as the OSHA reference and Garren '241, cannot be shown to establish obviousness absent some teaching, incentive, or

suggestion in these references. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1984); *In Re Fine*, 837 F.2d 1071 (C.A.F.C. 1988). This a second basic criteria required of *prima facie* obviousness. M.P.E.P. § 2142-43. In the present case, no indication is made as to where in any of the cited references the requisite teaching, incentive, or suggestion may be found. For this reason as well, the combination of references suggested by the Examiner does not provide a proper basis for a rejection under 35 U.S.C. § 103(a).

The application of an integrally formed, seamlessly joined combination in the pipette art does not necessarily, readily apply to the smoke tube art. Applicants believe that the smoke tube art is a unique, unsophisticated but mature art, wherein change and innovation are uncommon. The primary concern in the manufacture of the smoke tube has been low cost and guaranteed performance. These concerns have traditionally been addressed by the low-cost, two-piece squeeze pump-glass tube design, and no motivation or incentive has surfaced to modify or deviate from this simple but effective design.

Furthermore, no one has even contemplated the use of an integrally formed tube-and-pump apparatus because of the different properties that each component required. The pump or squeeze bulb must be formed from a flexible material that can be squeezed, while the tube portion must be formed from a material that is sufficiently impermeable so as to protect the chemical in the container portion from reacting with the local environment until the test is ready to be performed. These two necessary properties, flexibility and impermeability, are not usually found in one material, and so the general perception in the art taught away from the present invention. That is, the general perception taught that two separate components must be used – a pump and a container – and attached just prior to performing the test.

This perception (or mis-perception) was further supported by the availability of low cost, glass container portions. In fact, the glass smoke tube has been the only design for several decades. Applicants agree that integrally forming and joining seamlessly two components are not novel, and that, in fact, such a manufacturing technique has been known throughout the several decades that glass smoke tubes have been around. The fact that such a manufacturing variation has been available, however, further supports the argument that the application of that combination to the smoke tube art is non-obvious. A primary reason for this has been the perceived adequacy of the glass smoke tube. Another reason is a reluctance by manufacturers to risk trying a new design to address important health and safety issues:

1) to prevent leakage of potentially harmful chemical substances like stannic chloride, and 2)

to ensure the effectiveness of a safety device, such as a smoke tube, by preventing contamination of the reactive substance prior to test. Such a risk has potential for legal and financial liabilities.

Moreover, Applicants submit that the pipette art is associated with laboratory type equipment and is not necessarily related to the smoke tube/field equipment art. One difference is that the smoke tube art is generally an unsophisticated art primarily concerned with minimizing cost and risk. Also, the two arts define two separate marketplaces and class of users. Thus, those designers or users concerned with the smoke tube art, if motivated to address a problem or deviate from the glass tube solution, will not look to or necessarily happen upon, the teachings of the pipette art.

Applicants acknowledge that Garren '241 teaches the use of a material other than glass for a pipette. Applicants note, however, that the patent recites its primary objective as designing a pipette made of "an inert material, made sterile, and be manufactured inexpensively enough to be substantially equal in cost to a conventional glass pipette." See col. 1; ln. 66 –col. 2; ln. 3. Garren '241 further explains that the 'primary objective ...is to employ a method ...wherein the resultant overall costs of the pipette is at a level to successfully compete with the cost of conventional glass pipettes." One important distinction between the design criteria for a pipette and for a smoke tube is that a smoke tube demands a sealed internal environment including a reactive chemical substance, and a pump and container section combination which are in fluid communication. A pipette, on the other hand, requires a device for transferring a volume of fluid. Using the manufacturing method taught by Garren '241 to make the smoke tube of the OSHA reference does not satisfy this specific demand. Moreover, the teaching of Garren '241 is limited by its "low cost to attain simple function" objective. To expand the manufacturing method and design taught by the reference to include steps and features directed to creating a sealed, internal environment including a reactive chemical substance and a pump and container combination that are in fluid communication" would appear to deviate and violate the strict limitations of the reference's teachings.

Accordingly, one skilled in the smoke tube art would recognize that certain aspects of the Garren '241 teaching is limited to the pipette art and not particularly helpful in addressing problems in the smoke tube art. Again, an important distinction between the two arts is that the smoke tube demands a sealed internal environment including a reactive chemical

substance and which defines a pump and container section in fluid communication, and the pipette of Garren '241 does not. A pipette is required to transfer a volume of fluid (and thus, cannot be sealed). Garren '241 is not directed to a "sealed pipette filled with a substance" nor a smoke tube with a one-piece pump, polymeric pump and container portion defining a sealed environment and including a reactive chemical substance therein.

3) *The suggested combination of references do not show any reasonable expectation of success from the combination.*

To satisfy a third basic criteria of *prima facie* obviousness, one must show a reasonable expectation of success from the combination of the OSHA reference and Garren '241 or the modification of the OSHA reference to incorporate the teachings of Garren '241. Again, the cited references do not teach or suggest the proposed combination or modification. Thus, no reasonable expectation of success (or synergy resulting from the combination) can be found. Applicants further note that the requisite motivation or desirability of a combination cannot be derived from benefits resulting from the claimed combination when only the patent discloses those benefits or any reasonable expectation of success, as is the case here.

Even if all elements of claim 1 were available from the cited references, there is no teaching in the cited references, or from the general knowledge available to one of ordinary skill in the art, which would allow the teachings of these two references to be combined so as to produce a workable product according to the claimed invention. The polymeric pump and tube combination suggested by the Garren '241 reference would not preserve the chemical substance and would not control generation of the indicator gas. Specifically, the container portion would not provide the proper seal in the presence of an open pipette end and is susceptible to moisture contamination due to the permeability of the plastic pump and tube. These, in fact, are a problem and concern that discouraged manufacturers and users from employing anything but enclosed glass tubes and separate pumps.

Accordingly, the combination of the Garren '241 reference and the OSHA reference does not provide a proper basis for a rejection under 35 U.S.C. § 103(a). Withdrawal of the Examiner's rejection of independent claims 1 and 22, and claims dependent from these claims under 35 U.S.C. § 103(a) is respectfully requested.

With respect to independent claims 32 and 52, Applicants submit that neither the Perlman '344 reference nor the ASA '802 portion teaches or suggests a laminate that substantially encases the pump-container portion structure, as required by the amended claims. Example 4 of Perlman '344 refers only to prepackaging that is removed prior to an autoclaving process. Applicants also note that Perlman '344 is directed to laboratory equipment, which is not the relevant art, and not field instrumentation. As for the ASA '802 reference, the film disclosed therein is used only to cover a portion of the prepackaging and thus, does not completely encase the apparatus at any point.

Accordingly independent claims 32 and 52, claims dependent from these claims, are also patentable over the cited references.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Attached is a Credit Card Payment Form PTO-2038 in the amount of \$475.00 to cover the Petition for Extension of Time within the third (3) month.

The Commissioner is hereby authorized to charge any additional fees or credit any overpayments related to this request to Deposit Account No. **50-0997 (STRAUGH-P02054US1)**, maintained by Paula D. Morris & Associates, P.C.

The undersigned is available for consultation at any time, if the Examiner believes such consultation may expedite the resolution of any issues.

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Respectfully submitted,

By AGAL

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